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Original Article

Effect of oral contraceptives on balance in women: A randomized controlled trial

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ABSTRACT

Objective: To detect the effect of combined oral contraceptive pills (COC) on dynamic postural balance in healthy middle aged women.
Materials and methods: A prospective randomized controlled study included 200 patients classified into two groups. Group I received COC containing 30 μg of EE and 3 mg of drospirenone for 12 consecutive cycles and Group II received no treatment. Overall, medio-lateral and antero-posterior stability were measured using Biodex system after 12 months.
Results: There was a highly statistically significant difference between the 2 study groups regarding estradiol level (12.84 ± 1.96 vs. 38.86 ± 3.99, *P* value < 0.001) and progesterone level (0.52 ± 0.25 vs. 11.64 ± 4.53, *P* value < 0.001). There was a highly statistically significant difference between the 2 study groups regarding mediolateral stability (1.84 ± 0.23 vs. 2.40 ± 0.56, *P* value < 0.001), antereoposterior stability (1.91 ± 0.29 vs. 2.33 ± 0.61, *P* value < 0.001) or overall stability (2.42 ± 0.29 vs. 2.95 ± 0.53, *P* value < 0.001).
Conclusion: COC are effective method of contraception to improve postural balance and decrease risk of injury in normal and athletic women.
NCT02855294.

Introduction

Combination birth control pills are oral contraceptives that combine ethinyl estradiol and progestin. They differ in estrogen amount and the amount and type of progestin, that can causes different progestational, estrogenic, and androgenic effect [1].

The pill is the method most widely used by white women, women in their teens and 20s, never-married and cohabiting women, childless women and college graduates [2]. Four of every five sexually experienced women have used the pill [3].

It has been reported that both strength and injury occurrence can vary over the course of the menstrual cycle [4].

Female sex hormones (i.e. estrogen, progesterone and relaxin) fluctuate radically during the menstrual cycle and are reported to increase ligamentous laxity and decrease neuromuscular performance. Oral contraceptives stabilize hormone levels during the menstrual cycle and may function to either passively or actively affect postural balance [5].

Improved neuromuscular coordination may occur in women taking OC with a reduced number of premenstrual symptoms. However, the relationship between fluctuations in ovarian sex hormone levels and neuromuscular strategies has not been fully described [6].

Postural balance consists of the combination of visual, vestibular and somato-sensorial systems [7]. Balance has often been used as a measure of lower extremity function. Because balance is maintained in the closed kinetic chain and relies on the integrated feedback and movement strategies among the hip, knee, and ankle, balance can be disrupted by diminished afferent feedback or deficiencies in the strength and mechanical stability of any joint or structure along the lower extremity kinetic chain [8].

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The aim of the present study is to detect the effect of combined oral contraceptive pills on dynamic postural balance in healthy middle aged women.

Material and methods

This prospective randomized controlled study included women who attended the contraception and Gynecology clinics at Kasr El-Aini Hospital in Cairo, Egypt, between January 1, 2015, and July 31, 2016. The study was approved by the Kasr AlAiny local Ethical Committee and informed written consents were obtained from all participants after explaining the aim, risks and outcome of the study.

The 200 women included in the present study were 20–40 years of age; with body mass index less than 30 kg/m^2 had regular menstrual cycles, fully co-operative and can stand independently. Exclusion criteria included contraindications for contraceptive steroid use as genital or breast cancer and active liver disease, the use of any hormonal contraceptive or hormone medicated intra-uterine device 6 months prior to study initiation. Women with an abnormal cervical smear diagnosed during screening and those with skeletal deformity or using assistive devices, visual and vestibular system affection, cognition problems or having previous surgeries at their back and/or lower limb were also excluded.

All patients were subjected to full history taking, general, abdominal and local examination. Ultrasound scan, Pap smear, complete blood picture and liver functions were also done.

Participants were equally randomized using automated web-based randomization system ensuring allocation concealment into two groups. Group I received COC containing 30 μg of EE and 3 mg of drospirenone (Yasmin; Schering AG, Berlin, Germany) for 12 consecutive cycles. Each treatment cycle consisted of 3 weeks of pill treatment followed by a 1-week pill-free period. Group II received no treatment.

This study was conducted in balance laboratory Faculty of Physical Therapy, Cairo University, and collaborative work with the Faculty of Medicine, MUST University.

Sample size calculation was done based comparing anteroposterior, mediolateral, and overall joint stability between OCP users and non-users. Student's *t*-test for independent samples was chosen with α-error level fixed at 0.05 at 80% power and the groups are assumed to be of equal size. Using pilot study results, the mean ± SD of anteroposterior stability in OCP users was 1.9 ± 0.32 while in non-users it was 2.3 ± 0.65. Accordingly, we need to study a minimum of 42 OCP users and 42 non-OCP users to achieve the presumed statistical power. Similarly, the reported mediolateral stability was 1.9 ± 0.42 and 2.4 ± 0.56 respectively. Accordingly, the minimum sample size per group was 21. Regarding overall stability, the pilot study reported average was 2.4 ± 0.3 in OCP users and 3.0 ± 0.55 non-user group; resulted in a minimum sample of 14 participants in each study arm. Calculations were done using PS Power and Sample Size Calculations Software, version 3.0.11 for MS Windows (William D. Dupont and Walton D. Vanderbilt, USA).

Biodex Balance System is a dynamic postural stability assessment and training system. It is a device that objectively measures and records an individual's ability to maintain stability under dynamic stress. It is designed to stimulate joint mechanoreceptor and to promote reflex muscular activation necessary for joint stability. Also, it is useful in evaluating problems related to balance, proprioception and neuromuscular control [9]. The system measures, in degrees, the tilt about each 33 axis during dynamic conditions and calculates a medial/lateral stability index (MLSI), anterior/posterior stability index (APSI), and an overall stability index (OSI) [10].

Evening Blood sample was collected from each woman to limit the effect of hormone diurnal variations, for both groups samples have been collected at mid-luteal phase (20th to 23th days of the cycle).

The sample was allowed to clot in water bath at room temperature. The serum was separated using a centrifuge at 4000 rpm for 15 min then using the TKE 21 and TKPG 1 Kits in a low temperature air conditioned room to measure serum Estradiol and Progesterone levels.

Testing procedures was done at mid-luteal phase (20th to 23th days of the cycle). Each woman was received verbal explanation about the test steps. The woman was tested without footwear and with eyes opened. Two test trials were done before specific test condition for the purpose of instrument familiarity prior to data collection. A high stability level (stability level 8) and reduced test time (20 s) was chosen to avoid falling. Each woman was asked to perform two trial tests and their mean was calculated. Each test started with the balance platform in the locked position and standing on its center.

All woman were asked to stand on the platform of the BBS in an erect posture as possible and kept it all through the test duration (i.e. stand on both feet, chin in, shoulders were leveled, as well as, retracted, back was straight and knees were drawn backward). Hence, the support handle rails and display screen were adjusted according to the height of each examined woman.

Centering step: with the aim of positioning the center of gravity (COG) of the subject at the middle of her base of support between the two feet and recording the women's feet position. Centering was achieved by asking each woman to stand on the platform of the BBS while grasping the support handle rails by both hands while the platform was locked. Formerly, the platform was unlocked at stability level 8, the display screen showed a circle with a central cursor. At that time, the subject was asked to achieve a central position on the platform by shifting her feet position until she was able to keep the cursor (which represents the center of platform) centered on the circle that appeared on the display screen and correspondingly the platform was kept easily leveled.

Once centering was achieved and the cursor was in the center of the display screen, each woman was instructed to maintain her feet at that position constant until the end of test procedures. At that time, the platform was locked again to allow recording the feet angles and heel's coordinates from the platform grid. The heel's coordinates were determined by finding the location of the center of the back of each heel in relation to X and Y coordinates of the platform, while the feet angles were determined by finding a line on the platform parallel to the 2nd metatarsal bone of each foot. Then, the feet angles and heels coordinates for each woman were entered to the software of the BBS (Fig. 1).

Recording step, the platform advanced to an unstable state (stability level 8) and the subject was instructed to focus on the visual feedback screen (display screen) directly in front of her and attempted to maintain the cursor in the middle of the circle on the display screen, while she was standing without grasping the support handle rails and her both arms beside her body. Each woman repeated the test trial 2 times with 3 min rest in between each test trial and the mean of the 2 readings was documented.

Descriptive statistics and *t*-test for comparison of the mean age between both groups. *t*-Test for comparison of hormone levels and dynamic balance between both groups. The level of significance for all statistical tests was set at $P < 0.05$. All statistical measures were performed through the statistical package for social studies (SPSS) version 19 for windows.

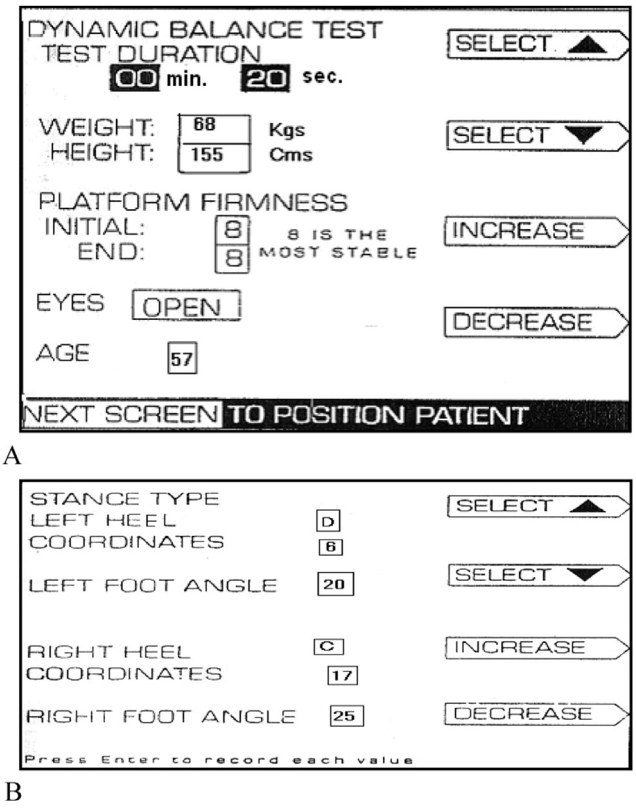

Fig. 1. A. The parameters of the dynamic balance test. B. Feet angles and heels coordinates on the BBS screen for an examined woman.

Results

The flow chart of the studied population is shown in Fig. 2.
There was no significant difference between the 2 study groups regarding age, parity or body mass index (Table 1).
There was a highly statistically significant difference between the 2 study groups regarding hormonal levels named estradiol and progesterone (Table 1).
There was a highly statistically significant difference between the 2 study groups regarding all stability indices whether mediolateral, antereoposterior or overall stability only after pill using (Table 2).

Discussion

In the current study, regarding the results of Biodex there was a significant decrease in overall stability index, medio-lateral stability and antero-posterior stability of OCP users when compared with controls; which mean increased postural balance control in oral contraceptive users. Also blood sample analysis referred significant low Estrogen (E2) and progesterone levels at mid-luteal phase of OCP users when compared with non-users.

The ability to maintain the position of the center of body mass within the stability limits is termed postural stability or balance. Postural control is defined as the ability to maintain control over posture and is a complex function involving the somatosensory, vestibular and visual systems as well as muscle activity [11].

These findings come in agreement with previous studies that have suggested that the variation of estradiol and progesterone during the menstrual cycle influences neurological and motor functions. Increased level of progesterone metabolites during the luteal phase are known to affect various transmitter and hormone systems, for example in the cerebellum, resulting in effects on motor function [11].

Rose in 2012 reported that Estrogen also has influence on the central nervous system and females have different skill performances during different phases of the menstrual cycle [12].

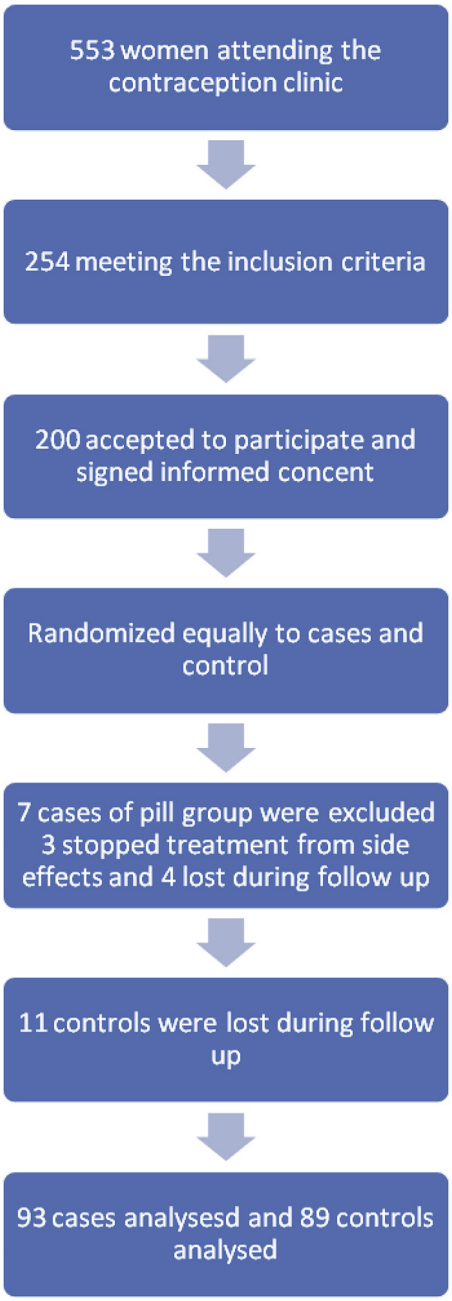

Fig. 2. Flow chart of the studied population.

Table 1
Characteristics of the study population.

	OCP Users	Controls	*P* value
Age (years)	28.8 ± 4.32	27.46 ± 3.81	0.37 NS
Parity	1.76 ± 0.98	1.95 ± 1.15	0.416 NS
BMI[a] (kg/m^2)	26.24 ± 1.20	26.43 ± 1.64	0.634 NS
P level (ng/ml)	0.52 ± 0.25	11.64 ± 4.53	0.0001 HS
E2 level (ng/ml)	12.84 ± 1.96	38.86 ± 3.99	0.0001 HS

Data are presented as mean ± SD.
[a] BMI: Body mass index.

Table 2
Stability index among the study groups.

		OCP Users	Controls	*P* value
Medio-lateral stability index	Before	2.37 ± 0.53	2.42 ± 0.55	0.71 NS
	After	1.84 ± 0.23	2.40 ± 0.56	<0.001 HS
Antero-posterior stability index	Before	2.38 ± 0.67	2.36 ± 0.61	0.8 NS
	After	1.91 ± 0.29	2.33 ± 0.61	<0.001 HS
Overall stability index	Before	2.97 ± 0.5	2.95 ± 0.52	0.88 NS
	After	2.42 ± 0.29	2.95 ± 0.53	<0.001 HS

Data are presented as mean ± SD.

Estrogen has effects on the central nervous system. It has demonstrated differences in skill performance in females during different phases of the menstrual cycle, also a decrease in motor skills in the premenstrual when compared to the late luteal phase. Estrogen influences electrical activity of neurons both centrally and peripherally [13]. Furthermore, postural control impairments have been demonstrated in females with premenstrual symptoms in the mid-luteal phase [14].

Posthuma et al., in 1987 found that the neuromuscular system is affected by the hormonal influence during the menstrual cycle and stated more consistent performance in women using oral contraceptive (OC) than non-users women. The benefit effect of OC is due to reduced variation of hormone change in menstrual cycle [15].

Darlington et al., in 2001 detected a greater postural sway in the luteal phase and the early follicular phase of the menstrual cycle. Since impaired postural control has been suggested as a part of the explanation for sports related injuries [16].

Agel et al., in 2006 stated that oral contraceptives control the hormone levels and phases across the menstrual cycle and limit hormone surges [17]. Also Diana et al., 2010 proved that hormonal contraceptives lower circulating levels of estrogen and progesterone [18].

Hewett, 2000 found that use of oral contraceptives may limit the potential influence of estrogen on factors which contribute to knee joint stability. Athletes on oral contraceptives demonstrate lower impact forces and reduced torques at the knee, increased quadriceps to hamstrings strength ratios, increased stability on one leg, and decreased knee laxity relative to non-users [19].

Martineau, 2004, proved that oral contraceptive pill use yielded statistically significant decreases in ligamentous laxity as compared with nonusers. The OCP may have a role to play in the prevention of injuries in athletic women [20].

Friden et al., proved that there is an increase in postural sway during single limb stance and threshold for detection of passive knee motion in the mid-luteal phase of the cycle [14,21]. As well as (Dedrick et al., 2008) discovered that improved neuromuscular coordination can occur in women taking OC with a reduced number of premenstrual symptoms [6].

However Wojtys et al., in 2002 found that women taking oral contraceptives had an injury rate much closer to the expected values than those not using OCP. These contradictions may be due to difference in the method used for assessment of postural balance and the smaller sample size [22].

The main limitation of our study was the inability to measure the hormonal levels at all stages of menstrual cycle and draw a curve all through follow up period to ensure stability in hormonal levels.

To the best of our knowledge, our study is the first randomized controlled trial to assess the effect of OCP on postural balance with adequate sample size and 12 months follow up duration.

We can conclude that combined oral contraceptives are effective method of contraception to improve postural balance and decrease risk of injury in normal and athletic women so it can be of great benefit to decrease injury levels in athletic females which is the result of reduced variability of hormonal levels and not the hormonal level itself.

Conflicts of interest

No conflict of interest.

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